UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,067	03/31/2004	Sin Chung	206,488	8461

7590 02/07/2006

ABELMAN FRAYNE & SCHWAB
150 East 42nd Street
New York, NY 10017-5612

EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/816,067	CHUNG, SIN	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *6-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/18/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-13 are pending in the application.

2. The Examiner to whom the case has been docketed in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Zachariah Lucas in Art Unit 1648.

Election/Restrictions

3. Applicant's election of Group I in the reply filed on December 12, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

4. Claims 6-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 12, 2005.

5. It is noted that claims 4 and 5 were previously included, respectively, in Groups II and III of the restriction requirement. It is unclear if these claims are directed to a composition, or a method of use. Because the claims appear to be directed to a composition with an intended use, the claims will be rejoined with claims 1-3 (identified as Group I) for the purposes of this action.

6. Claims 1-5 are under consideration.

Priority

7. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

8. The information disclosure statement (IDS) submitted on November 18, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims each read on the compositions as set forth in one of claims 1-3, wherein the composition is used to treat a disorder. It is unclear from the claims if they are directed at the compositions themselves, and are identifying an intended use thereof, or if the claims are directed to methods of using the compositions.

It is further noted, that if the later is the case (i.e. the claims are directed to a use, and not the compositions), then the claims appear to be improper use claims as not steps have been recited in the claims.

Clarification of the claim language is required.

For the purposes of this action, the claims will be treated as reading on the composition and identifying an intended use.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. he claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims are rejected because the application is not enabling for the use of any composition comprising any euglobulin.

In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Id. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered. In the present case, those factors considered most relevant

are the amount of guidance presented and the presence of working examples, the state of the prior art, and breadth of the claims.

The claims are directed to a composition comprising disrupted M. albicans and euglobulin. The application discloses the use of such compositions for the treatment of certain disorders, and demonstrates the efficacy of such compositions for the treatment of exemplary conditions in dogs. See e.g., pages 9-16. While the application demonstrates that certain embodiments of the claimed composition achieved beneficial results in dogs, there is not actual identification of the euglobulin used in the provided examples. I.e., the application does not identify the source of the euglobulin.

Euglobulin is a fraction of blood serum generally known in the art as a "fraction of the serum globulin less soluble in (NH4)2SO4 solution than the pseudoglobulin fraction." See e.g., The On-line medical dictionary. Thus, according to the present claims the euglobulin may be any such fraction of any serum composition from any number of animals, each of which has varying blood proteins and components. There is no description in the application identifying what components of the euglobulin were required to achieve the desired results. Nor is there any identification of the mode of operation of the composition administered. Although such a description is not required to demonstrate enablement, in the present case where the application is broadly claiming a genus of compositions based on the disclosure of a single and unknown species, such a disclosure would be useful to those in the art in determining which compositions would prove in the indicated methods. In short, the application provides only a single, and not fully described, working example, and provided no guidance as to what other euglobulins may be used or evidence to demonstrate that any euglobulin from any source may be used.

It is recognized in the art that proteins vary from animal to animal. See e.g., Heesen et al., J Immunol 157: 5455-60, abstract (teaching homologues of proteins found in humans and mice, but which differ in sequence and are not necessarily functionally interchangeable). Thus, those in the art would not assume that euglobulin from one source would necessarily be capable of performing the same functions as that from another source. Further, the art provides no teachings relating to the use of compositions such as those claimed for the indicated treatments. Thus, there is substantial unpredictability in the art regarding the substitution of one euglobulin fraction for another.

In view of the limited predictability and immature state of the art relating to the claimed invention, the provision of the single and poorly defined working example in the absence of additional guidance, and the breadth of the claims, the application does not provide sufficient information to enable those in the art to use the claimed compositions to the full extent as claimed. There is insufficient enabling support for the use of compositions comprising euglobulin from any source.

12. Claims 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims read on pharmaceutical compositions for the treatment of certain disorders comprising disrupted Monilia albicans cells and euglobulin (a fraction of blood serum). The claims are rejected because the application has not provided sufficient descriptive support

for a genus of compositions comprising any euglobulin (i.e. euglobulin from any source) that are useful for the treatment of the indicated disorders.

In making a determination as to whether a claimed invention has been adequately described to show that the applicant the courts have identified certain elements that may be considered. Among those elements are the knowledge in the particular field, the extent and content of the prior art, the maturity of the technology, and predictability of the aspect at issue. See e.g., *Capon v. Eshhar*, 76 U.S.P.Q. 2d 1078, at 1085 (CAFC 2005). More specific to generic claims, such as in the present case, the courts have also indicated that support for a genus may be provided through identification of representative number of species of the genus. See e.g., *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, at 1406 (CAFC 1997).

As indicated above, the claims are drawn to compositions comprising disrupted M. albicans cells and euglobulin. Euglobulin is a fraction of blood serum generally known in the art as a "fraction of the serum globulin less soluble in (NH4)2SO4 solution than the pseudoglobulin fraction." See e.g., The On-line medical dictionary. Thus, according to the present claims the euglobulin may be any such fraction of any serum composition from any number of animals, each of which has varying blood proteins and components.

In support of these claims, the application discloses the use of such a composition for the treatment of canine distemper virus infections, and certain neurological conditions, in dogs. See e.g., examples 4-7 (pages 9-16). However, each of these compositions uses euglobulin composition of unknown origins. There is no disclosure of either the components or the source of the euglobulin used in the disclosed examples. Thus, while the application has disclosed a species of the claimed genus, it is not clear what species has been disclosed. Nor does the

application provide any other means of identification of the claimed compositions other than the functional ability of the compositions to treat the indicated disorders.

However, the disclosure of a function without more is not sufficient to provide support for a genus of compositions. See, *Eli Lilly*, 43 U.S.P.Q.2d at 1406. While the disclosure of a function tied to some other characteristic may be sufficient, there is no demonstration in the present application that the use of any euglobulin would achieve the desired effects, or any identification of components or features of the disclosed euglobulin that correspond to its utility in the disclosed methods. Further, as was indicated above, those in the art would have little certainty that euglobulin from one source would be functionally equivalent to that from another source. See e.g., Heesen et al., J Immunol (supra- disclosing structural and functional variation in proteins from different animals). In view of this uncertainty, the limited teachings in the present application or in the art regarding the use of the claimed compositions and its operation, and the presence of only a single and poorly described embodiment of the claimed compositions, the present application does not provide adequate descriptive support for any composition comprising any euglobulin that would be capable of treating the indicated disorders.

13. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 5 is drawn to a pharmaceutical composition comprising disrupted M. albicans and euglobulins, wherein the composition is useful for the treatment of any of "cerebral apoplexy, brain injury, neurological

dysfunctions, Alzheimer's disease and myoclonus." The claim is rejected because the application has not demonstrated that the claimed composition would be useful for the treatment of all neurological disorders falling within the indicated group.

In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Id. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered. Those considerations deemed most relevant in the present case are the breadth of the claims, the amount of guidance presented, the presence or absence of working examples, and the state of the art.

As indicated above, the present claims are drawn to compositions comprising disrupted M. albicans and euglobulins that are effective for the treatment of a variety of neurological disorders or injuries. Each of the various conditions to be treated has a different cause. For example a brain injury results from physical damage to the brain, Alzheimer's results from chemical buildups within the brain, and "neurological dysfunctions" may result from anything from a pathogenic infection to a chemical or nutritional imbalance. Further, it is noted that there are no teachings in the art drawing any correlation between M. albicans to such disorders generally, nor any common factor among these conditions, other than that they generally affect

the neurological systems. Thus, the art relating to the claimed invention is relatively undeveloped and not understood.

The application asserts the claimed composition may be used for the treatment of any such neurological dysfunctions or conditions. In support of this, the Applicant presents data indicating that 70% of dogs suffering from various forms of neurological conditions achieved some improvement after administration of the claimed composition. See e.g., pages 15-16 (Example 7). However, the experimental data provides no information as to which dogs, suffering from which conditions, benefited from the administration. Because not all of the dogs benefited from the administration, the application provides evidence that not every neurological condition is subject to treatment with the claimed compositions. However, because the application does not disclose which dogs (or which disorders) were so susceptible, the application also fails to provide guidance to those in the art as to what disorders would be subject to treatment. In view of the evidence that not every neurological disorder would be subject to treatment, the scope of the claims such that they read on the treatment of any neurological condition, and because the application does not provide sufficient information to enable those in the art to determine which conditions would or would not be subject to treatment with the claimed compositions, the claims are rejected for lack of an enabling disclosure.

It is suggested that the functional language be removed from the claim.

14. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

inventor(s), at the time the application was filed, had possession of the claimed invention. he claim has been described above. As indicated above, it reads on a pharmaceutical composition claimed as effective for the treatment of a genus of conditions comprising almost any neurological condition.

The following quotation from section 2163 of the Manual of Patent Examination Procedure is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus... See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.
>
> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Thus, when a claim covers a genus of inventions, the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed.

However, the presence of multiple species with in a claimed genus does not necessarily demonstrate possession of the genus. See, In re Smyth, 178 U.S.P.Q. 279 at 284-85 (CCPA 1973) (stating "where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus or combination claimed at a later date in the prosecution of a patent application."); and University of California v. Eli Lilly and Co., 43

USPQ2d 1398, at 1405 (Fed Cir 1997)(citing Smyth for support). Thus, support for a generic invention may be found where a sufficient number of species have been disclosed to demonstrate possession of the genus as a whole so long as there is certainty in the art when expanding practice from the disclosed species to other species.

As was indicated above, the application demonstrates that certain neurological conditions are subject to treatment with the claimed composition. Example 7, pages 14-15. However, the application does not indicate which conditions were so susceptible, nor provide any means for distinguishing between conditions that are susceptible to such treatment from those that do not. Further, the experimental evidence provided by the application also demonstrates that not every neurological condition is so treatable by indicating that not every dog suffering a neurological condition benefited from the administration of the composition. In view of the evidence that the compositions would not be effective for the treatment of each of the identified conditions, the uncertainty in among the operation of the composition for the treatment of different neurological conditions, and because the application provides insufficient information to distinguish between conditions that are susceptible to treatment from those that are not, the application has not provided sufficient information to demonstrate possession of the claimed invention. The claim is therefore rejected as lacking sufficient written description support.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

16. Claims 1, 3, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Lott et al. (U.S. 5,688,644). These claims are directed to compositions comprising a disrupted cell suspension of Monilia albicans (another name for Candida albicans) and euglobulins (a fraction of serum proteins). This reference teaches a method for the preparation of a sample for an assay comprising the collection of blood in a tube, and subjecting the blood to treatment with a compound resulting in the lysis of C. albicans cells in the sample. See e.g. abstract. The reference therefore teaches a composition comprising disrupted C. albicans cells in solution. Further, the reference teaches that the solution is a blood solution, which would inherently include the euglobulin fraction of blood serum. Thus, the reference teaches a composition according to the rejected claims.

17. Claims 1, 3, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Bergeron et al. (U.S. 2003/0049636). The claims have been described above. Like the Lott reference above, this reference also teaches the lysis of C. albicans cells in a blood sample. See e.g., pages 11-12 (Examples 3, 6, and 8). Thus, the reference anticipates the indicated claims.

18. Claims 1, 3, 4, and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Picard et al. (U.S. 2004/0076990). The claims have been described above. The reference teaches a means for detecting C. albicans in a sample comprising a step of mechanically disrupting C. albicans cells in a blood sample. See, column 8, Example 7. As the reference teaches the disruption of the C. albicans cells while still present in combination with the blood sample, and as euglobulins would inherently be present in such a sample, the reference teaches a composition comprising the required components. Thus, the reference anticipates the indicated claims.

Conclusion

19. No claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

JAMES HOUSEL 2/6/06
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600